K070664

510(k) Summary

APR 26 2007

as required by CFR section 807.92(c)

I. General Information

Date: March 1, 2007

Applicant: Progeny, Inc.
1807 Barclay Blvd.
Buffalo Grove, Ill.
60089

Contact Person: Alan Krema

Telephone: 847-850-3800 x785

Fax: 847-850-3800

II. Names

Device Name:

Trade Name: PROGENY IMAGING SOFTWARE
Common Name: Exra Oral X-Ray System
Classification Name: 90 MUH Extra oral source x-ray system

III. Predicate Devices

Gendex Vix Win Pro
Schick CDR software

IV. Product Description

The Progeny, Inc. Progeny Imaging Software is a diagnostic imaging display of digitally acquired dental x-ray images. The software can also display images from intra oral video cameras.

V. Indications for Use / Rationale for Substantial Equivalence

The Progeny Imaging Software is to be used as a display of intraoral radiographic images in Dental radiography.

The Progeny Imaging Software shares the same indications for use, materials, design, operational and functional features and is therefore substantially equivalent to the predicate devices listed in section III of this summary.

There are several major independent manufacturers of Intra Oral diagnostic Radiographic software display systems on the U.S. market. One is the Gendex Vix Win Pro. The 510(k) number is K060178 . The classification of the Dentsply device is listed as product code 90 MUH.

Another currently marketed device is the Schick CDR software, manufactured by Schick, Inc. The 510(k) number is K022953. The classification of the Schick CDR is listed as product code 90 MUH .

Comparison Table:

Characteristic	Vix Win Pro	CDR	Progeny Imaging
	K060178	K022953	
Implementation	Software Only	Software and Sensor	Software Only
Computer	PC	PC	PC
Operating System	Windows 98, 2000, & XP	Windows 98, 2000, XP	Windows XP
Display Resolution	1024 x 768 true color recommended		SVGA
USB support	Yes	Yes	Yes
Ethernet support	No	No	Yes
Images Displayed	Dental x-rays, Intra oral images	Dental X-rays, Intra oral images	Dental x-rays, intra oral images

VI. Safety and Effectiveness Information

Safety and effectiveness is demonstrated by:

Performance testing and verification to meet product specifications.
Software testing to validate software design and performance.
Hazard analysis and risk level assessment.
Same indications for use as predicate devices.

All of the above steps and evaluations combine to demonstrate that the Progeny Imaging Intraoral Dental X-Ray Software is safe and effective when the device is used as labelled.

VII. Conclusion

The Progeny, Inc. Progeny Imaging Software is determined to be substantially equivalent to the predicate devices, the Gendex Vix Win Pro, and the Schick CDR software. The Progeny Imaging software shares the same indications for use, materials, design, operational and functional features to the currently marketed predicate devices listed in section III of this summary. The Progeny Imaging software is safe and effective when the device is used as labelled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Alan Krema
Director of Product Development
Progeny, Inc.
1407 Barclay Blvd.
BUFFALO GROVE IL 60089

APR 26 2007

Re: K070664
Trade/Device Name: Progeny Imaging software
Regulation Number: 21 CFR §872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 28, 2007
Received: March 9, 2007

Dear Mr. Krema:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070664

Statement of Indications for Use: K070664

Intended Use for the Progeny Imaging software:

The intended use of the Progeny Imaging software is to act as a diagnostic imaging display of digitally acquired dental x-ray images. The software can also display images from intra oral video cameras.

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070664